

## **REMARKS**

### **I. Introduction**

Applicant has amended the priority claim and summary of the Invention to correct typographical errors as suggested by the Examiner. In addition, claims 1, 2, and 34 have been canceled and new claims 35 and 36 have been added. Support for new claim 35 can be found in the specification as originally filed at, for example, page 6, lines 27-28, page 7, lines 2-3, page 10, lines 1-3 and page 8 lines 14-16. Support for new claim 36 can be found in the specification as originally filed at, for example, page 10, lines 1-3.

### **II. The objection to the specification may be withdrawn.**

The Examiner objected to the specification for containing two typographical errors. First, the terms "patent application" were not capitalized in the priority claim as filed in Applicant's Preliminary Amendment of December 20, 2001. Second, Applicant inadvertently recited the incorrect SEQ ID NOs at the first paragraph of the Summary of the Invention. As indicated in the instant amendment, Applicants submit that the aforementioned formalities have been corrected in accordance with the Examiner's suggestions. Accordingly, the Examiner's objection to the specification may be withdrawn.

### **III. The objection to claims 1, 2, and 34 may be withdrawn.**

The Examiner objected to claims 1 and 34 for failure to define the abbreviation "PDE10 polypeptide" as "phosphodiesterase 10 (PDE10)." In response, claims 1 and 34 have been canceled and new claims 35 and 36 have been added. Applicant submits that new claims 35 and 36 do not recite the abbreviation "PDE10," and thus do not require the definition suggested by the Examiner. The Examiner objected to claim 2 for incorrectly reciting SEQ ID NOs that relate to nucleic acid sequences. In response, Applicant canceled claim 2 and points out that new claims 35 and 36 recite SEQ ID NOs that relate to the appropriate amino acid sequences. Accordingly, the Examiner's objection to the claims 1, 2, and 34 may be withdrawn.

### **IV. The rejection of claim 34 under 35 U.S.C. §101 may be withdrawn.**

The Examiner rejected claim 34 for allegedly being directed toward non-statutory subject matter. Although Applicant has canceled claim 34, the Examiner's suggestion of amending claim 34 to recite the limitation of "an isolated and purified"

polypeptide has been incorporated into new claim 35. Accordingly, the rejection of claim 34 under 35 U.S.C. §101 may be withdrawn.

**V. The rejection of claims 1, 2, and 34 under 35 U.S.C. §112, second paragraph, may be withdrawn.**

The Examiner rejected claim 1, and thus claim 2 dependent therefrom, as allegedly being indefinite for the recitation of the term "PDE10." The Examiner stated that the specification failed to teach identifying characteristics which would distinguish a "PDE10 polypeptide" from other phosphodiesterases. At the outset, Applicant points out that claims 1 and 2 have been canceled. Further, new claim 35 does not recite the term "PDE10." Unlike canceled claim 1, new claim 35 is limited to specific SEQ ID NOs and polynucleotides that hybridize thereto under specific conditions.

The Examiner rejected claim 34 for "...the recitation of the phrase "moderately stringent hybridization conditions" as the specification does not define what conditions constitute "moderately stringent." In response, Applicant points out that the parent U.S. patent (6,350,603; hereinafter the '603 patent) of the instant application contains claims with similar hybridization language. Specifically, claim 3 of the '603 patent states:

3. A polynucleotide encoding a human phosphodiesterase 10 (PDE10) polypeptide with PDE10 enzymatic activity selected from the group consisting of:
  - a) the polynucleotide according to claim 2;
  - b) a polynucleotide encoding a polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 2, SEQ ID NO: 19, SEQ ID NO: 21 and SEQ ID NO: 23, and
  - c) a DNA which hybridizes under moderately stringent conditions to the non-coding strand of the polynucleotide of (a) or (b); said moderately stringent conditions comprising a final wash at 65 degrees C. in 2X SSC and 0.1% SDS. (emphasis added)

Notwithstanding the similarity between the issued claims in the '603 patent with the instant claims, Applicant submits that the final wash conditions are, in fact, indicative of the stringency of the hybridization conditions. It is inconsequential whether initial hybridization conditions are recited since it is the final washing step that ultimately determines the stringency of the conditions (i.e., the minimal degree of complementarity that will be tolerated to form hybridization products and therefore which polynucleotides will hybridize).

Accordingly, the rejection of claims 1, 2, and 34 under 35 U.S.C. §112, second paragraph, may be withdrawn.

**VI. The rejection of claims 1, and 34 under 35 U.S.C. §112, first paragraph, may be withdrawn.**

The Examiner rejected claims 1 and 34 as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner stated that the specification fails to teach any particular structure/function relationships in the four species disclosed in the specification and fails to describe additional representative species of these polypeptides by any identifying structural characteristics or properties other than sequence, for which no predictability of structure is apparent. The Examiner further rejects claims 1 and 34 because the specification allegedly fails to provide enablement for "any PDE10 polypeptide" (Office Action page 6) and further fails to provide support for "...the broad scope of the claims which encompass all modifications and fragments of any PDE10 polypeptide..." (Office Action, page 8).

First, Applicant again points out that claims 1 and 34 have been canceled. New claim 35, and new claim 36 dependent therefrom, recite the limitation of "with phosphodiesterase enzymatic activity." Thus, unlike canceled claims 1 and 34, the recitation in new claim 35 of specific SEQ ID NOs, hybridization conditions, and a specific enzymatic activity, are sufficient to convey to one of ordinary skill in the art that the inventors had possession of the claimed invention at the time the application was filed. In support of this argument, Applicant points to Example 9 of the Revised Interim Written Description Guidelines. According to Example 9, a claim that recites a specific sequence and hybridization conditions in combination with a specific activity of the encoded polypeptide is adequately described according to the written description requirements:

Now turning to the genus analysis, a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention. (Example 9, Pages 36-37)

Applicant also points to the issued claims in the '603 patent and applicants arguments in section V above. Accordingly, the rejection of claims 1, and 34 under 35 U.S.C. §112, first paragraph, may be withdrawn.

**VII. The rejection of claims 1, and 34 under 35 U.S.C. §102(e) may be withdrawn.**

The Examiner rejected claims 1 and 34 under 35 U.S.C. §102(e) as being anticipated by Fisher et al. (U.S. Patent No. 5,922,595; hereinafter the '595 patent)). The application which ultimately gave rise to the '595 patent was filed on December 9, 1997. In response, Applicant submits a copy herewith of a declaration under 37 C.F.R. §1.131 executed by Dr. Kate Loughney on April 26, 2000. The original declaration was filed during prosecution of the parent application (U.S.S.N. 09/256,000, now the '603 patent). In view of the attached declaration, the '595 patent is an improper reference against the claimed subject matter. As evidenced by the declaration, the subject matter of the claims was conceived and reduced to practice at least as early as the effective filing date of the cited patent. The Applicant therefore submits that the rejection of claims 1 and 34 under §102(e) must be withdrawn.


**VIII. Conclusion**

The Examiner noted that the listing of references in the specification is not a proper information disclosure statement pursuant to 37 C.F.R. §1.98(b). Accordingly, the Applicant files herewith a PTO-1449 form and proper information disclosure statement.

In view of the amendments and remarks made herein, the Applicant believes that claims 35 and 36 are in condition for allowance and respectfully request notification of the same.

Respectfully submitted,  
MARSHALL, GERSTEIN & BORUN LLP  
6300 Sears Tower  
233 South Wacker Drive  
Chicago, Illinois 60606-6357  
(312) 474-6300

By:

  
Eric M. Brusca  
Reg. No. 52,664

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